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Aromatherapy versus Oral Ondansetron for Antiemetic Therapy Among Adult Emergency Department Patients: A Randomized Controlled Trial.

Michael D. April, MD, DPhil, MSc; William T. Davis, MD; Curtis J. Hunter, MD, FACEP; Patrick C. Ng, MD; Joshua J. Oliver, MD; David Ong, MD; Erica M. Simon, MD
Department of Emergency Medicine, San Antonio Uniformed Services Health Education Consortium

Introduction

- Isopropyl alcohol is inexpensive and reported by multiple trials to have efficacy in treating post-operative nausea and vomiting.
- A single ED randomized controlled trial demonstrated superior treatment of nausea with inhaled isopropyl alcohol compared to inhaled saline placebo.
- Chief complaints related to nausea or vomiting account for approximately 4.8 million ED each year in the United States
- The goal of this study is to compare nasally inhaled isopropyl alcohol versus oral ondansetron in treating nausea among ED patients

Methods

- Single center placebo-controlled blinded RCT
- Convenience sample of adults presenting to the ED with chief complaints including nausea or vomiting
- Three arms: (1) inhaled isopropyl alcohol and oral placebo; (2) inhaled isopropyl alcohol and 4 mg oral ondansetron; (3) inhaled saline placebo and 4 mg oral ondansetron
- The primary outcome was the change in subject-reported nausea from baseline to 30 minutes post-intervention as reported on a 100 mm visual analog scale
- Secondary outcomes included change in pain VAS score from baseline to 30 minutes post intervention, vomiting during ED stay, receipt of rescue anti-emetics, admission to the hospital, ED length of stay, and final nausea, pain, and satisfaction VAS scores.

Results

Figure 1. Subject Enrollment

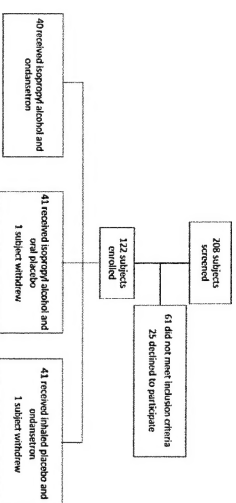
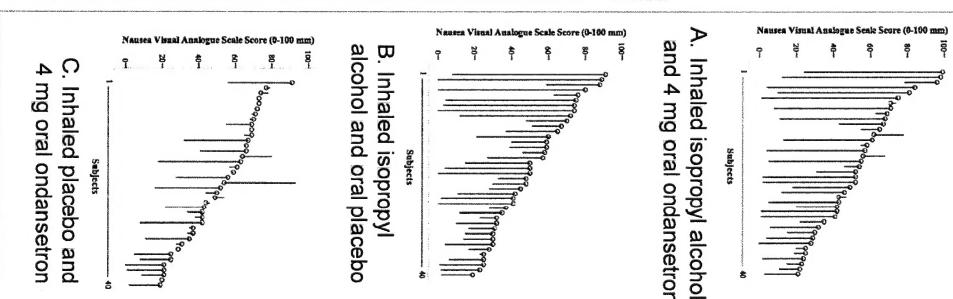


Table. Baseline characteristics and outcomes

	Inhaled Isopropyl Alcohol + Oral Ondansetron (n=40)	Inhaled Isopropyl Alcohol + Oral Placebo (n=40)	Inhaled Placebo + Oral Ondansetron (n=40)
Baseline Characteristics			
Age, mean (SD), y	30.5 (10.9)	34.2 (15.5)	29.25 (10.6)
Female sex (95% CI), %	50 (33.8-66.2)	35.0 (20.6-51.7)	52.5 (36.1-68.5)
Weight, kg	77.5 (16.9)	78.1 (19.4)	83.7 (18.8)
Symptom duration, hr	13.5 (6-48)	24 (6-72)	19 (10-48)
Vomited since symptom onset, %	82.5 (67.2-92.7)	73.2 (57.9-84.4)	73.6 (59.7-87.6)
Initial nausea score, VAS	52.6 (21.7)	50.8 (20.7)	51.2 (19.7)
Initial pain score, VAS	37.3 (31.3)	39.4 (27.9)	43.5 (29.1)
Outcomes			
VAS nausea score reduction at 30 min	29.6 (26.5)	31.9 (23.0)	9.4 (16.0)
VAS pain score reduction at 30 min	9.8 (20.9)	11.1 (15.9)	2.9 (14.0)
Final nausea VAS score	15.8 (19.4)	16.3 (18.3)	29.3 (24.0)
Final pain VAS score	17.8 (20.8)	21.9 (21.1)	29.9 (26.8)
Nausea therapy satisfaction VAS	80.9 (28.5)	77.9 (28.8)	55.9 (35.5)
Vomited in ED, %	7.5 (1.6-20.4)	0.0 (0-10.4)	7.5 (1.6-20.4)
Receipt of rescue anti-emetics, %	27.5 (14.6-43.9)	25.0 (12.7-41.2)	45.0 (29.3-61.5)
ED length of stay, min	217 (140)	224 (136)	210 (112)
Admitted (95% CI), %	12.5 (4.2-26.8)	0.03 (0.0-13.2)	0.00 (0-10.4)

Figure 2. Nausea Visual Analogue Scores



Results

Table 3. Effect size differences compared with arm receiving inhaled placebo and oral ondansetron.

Variables, mean (95% CI)	Inhaled Isopropyl Alcohol + Oral Ondansetron (n=40)	Inhaled Isopropyl Alcohol + Oral Placebo (n=40)
VAS nausea score reduction at 30 min	20.2 (10.4 to 29.9)	22.5 (13.7 to 31.3)
VAS pain score reduction at 30 min	6.9 (-1.0 to 14.8)	8.2 (1.6 to 14.9)
Final nausea score, mean (95% CI), VAS*	-13.4 (-23.4 to -3.5)	-13.0 (-22.7 to -3.2)
Final pain score, mean (95% CI), VAS*	-12.1 (-22.7 to -1.4)	-8.0 (-18.7 to 2.7)
Nausea therapy satisfaction VAS	25.0 (19.4 to 30.5)	21.9 (16.1 to 27.8)
Vomited during ED stay (95% CI), %	0.0 (-1.9 to 11.9)	-7.5 (-15.9 to 0.9)
Receipt of rescue anti-emetics (95% CI), %	-17.5 (-38.8 to 3.8)	-20.0 (-41.8 to 1.0)
ED length of stay, mean (95% CI), min	6.2 (-50.2 to 62.5)	13.6 (4.1 to 68.9)
Admitted (95% CI), %	12.5 (2.0 to 23.0)	2.5 (-2.5 to 7.5)

Discussion

- Subjects receiving isopropyl alcohol had greater nausea relief than subjects receiving ondansetron
- The mechanism of action of isopropyl alcohol is unknown
- No adverse events were reported by study subjects
- Subjects were provided additional isopropyl alcohol or placebo pads on request to allow repeated dosing

Conclusions and Future Directions

- In this ED population of patients not requiring immediate IV access, isopropyl alcohol was superior to ondansetron in treating nausea
- Additional study is needed to compare aromatherapy to intravenous therapy
- Triage protocols enabling the administration of isopropyl alcohol to patients with nausea upon ED arrival is a practical application of these findings